

1 **Saul Perloff (157092)**
 2 saul.perloff@aoshearman.com
 3 **Katharyn Grant (pro hac vice)**
 4 kathy.grant@aoshearman.com
 5 **Andre Hanson (pro hac vice)**
 6 andre.hanson@aoshearman.com
 7 **Olin "Trey" Hebert (pro hac vice)**
 8 trey.hebert@aoshearman.com

ALLEN OVERY SHEARMAN STERLING
US LLP
 300 W. Sixth Street, 22nd Floor
 Austin, TX 78701
 Telephone (512) 647-1900

9 **Christopher LaVigne (pro hac vice)**
 10 christopher.lavigne@sherman.com

ALLEN OVERY SHEARMAN STERLING
US LLP
 599 Lexington Ave
 New York, NY 10022
 Telephone (212) 848-4000

11 Attorneys for Plaintiff/Counterclaim-Defendant
 12 GUARDANT HEALTH, INC.

13 GUARDANT HEALTH, INC.

14 Plaintiff and
 15 Counterclaim-Defendant,

16 vs.

17 NATERA, INC.

18 Defendant and
 19 Counterclaim-Plaintiff.

20 **Jennifer L. Keller (84412)**
 21 jkeller@kelleranderle.com
 22 **Chase Scolnick (227631)**
 23 cscolnick@kelleranderle.com
 24 Craig Harbaugh (194309)
 25 charbaugh@kelleranderle.com
 26 Gregory Sergi (257415)
 27 gsergi@kelleranderle.com
 28 **KELLER/ANDERLE LLP**
 29 18300 Von Karman Ave., Suite 930
 30 Irvine, CA 92612
 31 Telephone (949) 476-0900

32 Case No. 3:21-cv-04062-EMC

33 **GUARDANT'S OPPOSITION TO**
 34 **NATERA'S MOTION TO EXCLUDE**
 35 **TESTIMONY FROM DR. CLAUS**
 36 **LINDBJERG ANDERSEN**

37 Motion Hearing: Nov. 4, 2024, at 8:30 am
 38 Trial Date: November 5, 2024

1 Guardant respectfully opposes Natera's motion to exclude from trial testimony secured
 2 from Dr. Claus Lindbjerg Andersen, Dkt. 763 ("Motion").

3 **I. Introduction**

4 This Court repeatedly authorized the deposition of Dr. Andersen, both in the original
 5 Letters of Request, Dkt. Nos. 153 and 157, and most recently in its Minute Order memorializing
 6 its Order excluding post-COBRA evidence:

7 Guardant may depose Dr. Anderson, and the Parties may use the deposition
 8 testimony at trial if otherwise admissible. This deposition pertains to the Reinert
 9 study in 2018-2019 and has nothing to do with COBRA.

10 Dkt. 719 (Oct. 15, 2024) at 2.

11 Dr. Andersen's testimony is admissible, relevant, and indeed critical. His testimony
 12 addresses key issues with respect to both Parties' claims, including how the authors of the Reinert
 13 study, in describing their own study as "prospective" and "blinded," understood the terms (and
 14 contradicts how Natera's other witnesses have testified about such issues). He also was emphatic
 15 that comparisons based on two studies that used disparate volumes of blood was an unfair "apples
 16 to pears" comparison. Dkt. 763-3 (Andersen Dep., Oct. 23, 2024) at 105:1-8.

17 Natera's primary opposition Dr. Andersen's testimony is that it is not the official
 18 "summary" of the Danish Court. But Fed. R. of Civ. P. 28(b)(4) provides:

19 (4) *Letter of Request—Admitting Evidence.* Evidence obtained in response to a
 20 letter of request need not be excluded merely because it is not a verbatim transcript,
 21 because the testimony was not taken under oath, or because of any similar departure
 22 from the requirements for depositions taken within the United States.

23 Here, even those limitations are not present: Dr. Andersen's testimony was taken under oath. At
 24 Natera's insistence, Dr. Andersen's testimony was in Danish, rather than in the English in which
 25 Dr. Andersen is fluent. Dr. Andersen's testimony was translated at his deposition by a certified
 26 interpreter, Ms. Susanne Frank, who is regarded as one of the best Danish to English translators in
 27 Denmark. That translation was provided to Natera's counsel in real time. At no point during Ms.
 28 Frank's translation did Natera's counsel complain that it was inaccurate. Dr. Andersen's testimony
 was transcribed—also in real time and the transcription certified, by Ms. Sherry Yan, trained in
 U.S. court reporting, whom Guardant flew from Ireland to be present at Dr. Andersen's testimony.

1 Again, the real-time, rough, and final transcription was provided to Natera's counsel, without
 2 objection. While Natera now purports to assert there are a few errors in Ms. Yan's transcription, it
 3 provides no information regarding Natera's purported counter-translation, and indeed fails even to
 4 identify the translator.

5 The Court should allow the use of Dr. Andersen's testimony, as translated and transcribed
 6 during his deposition, at trial.

7 **II. Dr. Andersen's deposition was taken under oath, translated by a certified
 8 interpreter, and transcribed by a U.S.-qualified court reporter.**

9 The Court is aware of the many hurdles Guardant overcame to obtain the sworn testimony
 10 of Dr. Andersen, the principal author of the Reinert Study. E.g., Dkt. 622 (Aug. 13, 2024) (status
 11 update regarding Letters of Request); Dkt. 664 (Sept. 19, 2024) (further status update regarding
 12 Danish Discovery). Indeed, as recently as September 23, 2024, Natera continued to raise objections
 13 before the Danish Court. *See* Ex. A att'd to Hebert Decl. at 2 (Natera's argument to Danish Court
 14 that: "Guardant has not met its burden of proving that the examination of Dr. Andersen is material
 15 to the US trial and has not sufficiently stated the facts sought to be proved by this examination.")
 16 Natera specifically "object[ed] to allowing Guardant's American lawyers to conduct the
 17 questioning," *id.* at 2, and further insisted that the examination be conducted exclusively in Danish,
 18 despite Dr. Andersen's fluency in English. *Id.* at 3. After arguing that only the parties' Danish
 19 counsel could question Dr. Andersen, Natera asserted Guardant's Danish counsel was not
 20 permitted to access the materials necessary to question Dr. Andersen.

21 On October 23 & 25, 2024, Dr. Andersen appeared at the Magistrates Court in Viborg,
 22 Denmark. As Natera insisted, Guardant's Danish lawyers questioned Dr. Andersen, and the
 23 testimony was in Danish. The testimony was simultaneously translated by Ms. Susanne Frank. *See*
 24 Dkt. 763-3 (Tr. of Andersen Dep., Oct. 23, 2024), and Dkt. 764-4 (Tr. of Andersen Dep., Oct. 25,
 25 2024). As reflected in her CV, Ex. B, Ms. Frank is "a certified conference interpreter to the EU
 26 institutions," and she is fluent in Danish and English. She is "a sworn interpreter and translator in
 27 Denmark," and she works "predominantly in the legal system," were she "specialized in criminal
 28 law and organized crime investigations . . ." *Id.* Her credentials include a Masters Degree in

1 International Business Communication (translation and interpreting), and over a dozen years of
 2 working as a Court and Police Interpreter and Conference Interpreter. *Id.* Ms. Frank's simultaneous
 3 translation was made available in real time to Natera's counsel, who were provided headsets by
 4 the Danish Court. Ms. Frank's translation was also transcribed by a U.S.-qualified court reporter,
 5 Ms. Sherry Yan, who Guardant brought from Ireland to Denmark to transcribe Dr. Andersen's
 6 testimony. She has certified the transcriptions of both days of the proceeding. *See* Ex. C.

7 **III. Dr. Andersen's deposition testimony is extremely relevant to numerous key issues**

8 Dr. Andersen testified about how the Reinert Study described itself as "blinded," but then
 9 explained how Natera was actually unblinded to the sample order before providing results from
 10 Signatera, and that Natera conducted numerous re-analyses and changed results after being
 11 unblinded. While he initially testified that Natera was only unblinded to sample order on March
 12 27, 2018, Dkt. 763-3 (Andersen Dep., Oct. 23, 2024) at 31:16-23, Dr. Andersen later admitted
 13 Natera was unblinded to the sample order more than two months earlier, on January 19, 2018,
 14 more than two months before Natera produced the initial results from Signatera. Dkt. 763-4
 15 (Andersen Dep., Oct. 25, 2024) at 149:17-150:17 ("Oh my goodness, we did it. That's what we
 16 did."). Indeed, Dr. Andersen was visibly shocked that Natera in fact had been unblinded to the
 17 sample order before providing the results.

18 Moreover, Dr. Andersen testified that Natera continued to adjust its assay's results that
 19 would be reported in the Reinert Study after being unblinded to the clinical outcomes:

20 Q. You confirmed on Wednesday and previously as well by accepting and standing
 21 by your declaration that **Natera reanalyzed some of the tests after being**
 22 **unblinded; correct?**

23 A. Yes.

24 Q. And you confirmed that after my rendition and your memory was jogged that
 25 you were also—that **you also agreed that their reanalysis of some of the**
 26 **patients' tests changed some of the ctDNA results?**

27 A. Yes. Yes. Yes.

28 Dkt. 723-4 (Andersen Dep., Oct. 25, 2024) at 146:8-21 (emphasis added). Dr. Andersen further
 confirmed that some changes to the ctDNA results reported in the Reinert Study were made after
 Natera was unblinded *and* were based on results from an experimental version of the assay (called

1 “Pool 2”) designed in coordination with Aarhus University (not Signatera) *after Natera learned*
 2 *which patients would recur.* Dkt 763-3 (Andersen Dep. Oct. 23, 2024) at 76:13-15 (Pool 2 designed
 3 after unblinding); *id.* at 90:16-23 (Pool 1 and Pool 2 data pooled into one); *id.* at 77:6-9.

4 Dr. Andersen’s testimony is all the more important because it contradicts that of Natera’s
 5 other witnesses. E.g., Rabinowitz Dep. 127:18-128:2 (criticizing Parikh Study as “unblinded”
 6 because “if you know that those patients have recurred, you absolutely cannot say that a study was
 7 blinded”); *id.* at 131:2-8 (“But I can say this: If we say that a test is blinded, we report the results
 8 when the -- when the results are blinded, and we would find out anything about the result reporting
 9 after the results are unblinded, and we then would not change our results or not do subsequent
 10 work on the samples. So I mean, it’s pretty basic. We don’t lie about samples being blinded. It’s
 11 very basic.”); *see also* Moshkevich Dep. 82:14-83:2; Sharma Dep. at 85:5-19.

12 Dr. Andersen’s testimony is also relevant to showing the falsity of Natera’s comparative
 13 advertisements. For example, he testified why it was important to have a minimum of 8 mL of
 14 plasma in the Reinert Study:

15 Because when looking for cancer DNA in the blood, it’s needed. · The blood doesn’t
 16 contain a lot of cancer DNA. So that the material you are able to extract has to be
 17 on a certain scope to be able to determine if the testing is available. . . .

18 That is what we needed in order to compare our test results with Natera’s, we needed
 19 to be able to analyze 8 millimeters.

20 Had we been using less, we would’ve known that the test would have been less
 21 likely to provide us with the same quality.

22 Dkt. 763-3 (Andersen Dep., Oct. 23, 2024) at 21:22-23:20; *id.* at 26:1-4 (“Q. So these patients,
 23 where it has been specified that it was 4 milliliters of less, they were excluded from the Reinert
 24 Study? A. As far as I remember, yes.”) He also explained that it is important, as he had advised
 25 Natera, to not compare results from studies that used different sample volumes:

26 If you give the possibility of analyzing 8 milliliters of plasma from the same person
 27 on the same blood sample, using one milliliter of plasma for another test based on
 28 the same principle, then the test that has eight times as much material also have
 29 eight times as much likelihood of showing something; therefore, you cannot
 30 compare head to head. You should’ve made a comparison with 8 milliliters in each.

1 *Id.* at 105:14-22. Accordingly, “compar[ing] Signatera’s performance with another test using less
 2 blood” “would be comparing apples and pears.” *Id.* at 105:1-8.¹

3 Dr. Andersen also testified what it means for a study to be “prospective.” Dkt. 763-3
 4 (Andersen Dep., Oct. 23, 2024) at 150:20-1. He confirmed that the Reinert Study did not have a
 5 statistical analysis plan in advance, *id.* at 96:21-24, though the authors “knew what kind of
 6 statistical analysis we wanted to make. · We had thought about it. · It was not formulated in writing,
 7 and it wasn’t published in a journal, and therefore, in a classical sense, an SAP does not exist, but
 8 of course we did have one.” Dkt. 763-4 (Andersen Dep., Oct. 25, 2024) at 76:14-25.

9 **IV. The transcript of Dr. Andersen’s deposition is admissible and will be more helpful to**
 10 **the jury than the Danish Court’s summary**

11 Natera’s objection to the use of Dr. Andersen’s actual testimony relies, first, on a misplaced
 12 insistence that as an “official” record, the Danish Court’s summary of Dr. Andersen’s testimony
 13 somehow will serve the jury here in its fact-finding better than the testimony itself. Motion at 1-2.
 14 But it is *this* Court, not the Magistrate in Viborg, Denmark, that is empowered to “exercise
 15 reasonable control over the mode and order of examining witnesses,” in order to “make those
 16 procedure effective for determining the truth.” Fed. R. Evid. 611(a)(1). While summaries of
 17 testimony *may* be admissible in some circumstance, they are scarcely preferred. E.g., *Planned*
 18 *Parenthood of Columbia/Willamette, Inc. v. Am. Coal. of Life Activits*, 290 F.3d 1058, 1116-17
 19 (9th Cir. 2002) (*en banc*) (Berzon, J., dissenting) (“substituting summaries of testimony for a word-
 20 for-word transcript itself can hardly serve as an ‘effective’ mode ‘for the ascertainment of truth’”).

21 To be clear, the availability of an “official” summary in no way precludes use of a verbatim
 22 transcript. In fact, the Federal Rules anticipate that depositions taken in foreign countries pursuant
 23 to a Letter of Request may differ somewhat from a deposition taken in this country, but gives this
 24 Court ample discretion to admit the testimony notwithstanding these differences: “Evidence
 25 obtained in response to a letter of request need not be excluded merely because it is not a verbatim

26
 27 ¹ Dr. Andersen also acknowledged that the lead-time of a test in a given study is dependent on
 28 frequency of scans. Dkt. 763-3 (Andersen Dep., Oct. 23, 2024) at 111:25-113:1 (acknowledging
 that “the frequency of testing influence[s] the lead time,” and explaining why Signatera’s lead time
 in the Henriksen 2 Study was half that of Signatera’s lead time in the Reinert Study).

1 transcript, because the testimony was not taken under oath, or because of any similar departure
 2 from the requirements for depositions taken within the United States.” Fed. R. Civ. P. 28(b)(4).
 3 That there *is* a “verbatim transcript” and the testimony *was* “taken under oath” is all the more
 4 reason that this actual testimony should be admissible.

5 Natera also complains that Ms. Frank, the interpreter, is somehow unqualified and was not
 6 separately sworn. Motion at 5. But her CV illustrates her ample qualifications. *See* Ex. B; *see also*,
 7 e.g., *Romero v. RBS Constr. Corp.*, No. 18-cv-0179, 2022 WL 522989, at *8 (D.D.C. Feb.22,
 8 2022) (qualified translator need only be “competent”). Moreover, Ms. Frank’s position is that of a
 9 certified, “sworn” translator, who regularly appears in court. Ex. B. Ms. Frank accordingly
 10 appeared at the deposition in Denmark, her translation took place in live court, and her translation
 11 was available to Natera’s US and Danish counsel *at the deposition*. Natera raised no objections to
 12 either her presence or the accuracy of her translation. While Guardant is of course happy to provide
 13 a supplemental sworn statement from Ms. Frank averring that she faithfully translated the
 14 questions and answers of Dr. Andersen’s testimony, e.g., *Lakah v. UBS AG*, 996 F. Supp. 2d 250,
 15 258 (S.D.N.Y. 2014) (supplemental declaration “cure[d]” any objection), Natera cannot plausibly
 16 suggest that this highly credentialed, independent professional would have done anything less.

17 Finally, Natera claims, on what it belatedly acknowledged, in a late-hour email, was a
 18 rough translation from unspecified staff at its own Danish counsel, that it “potential[ly]” disagrees
 19 with a handful of Ms. Frank’s translations. *See* Motion at 5-6. Natera fails to note that almost half
 20 of the potentially disputed cites are not even found in Guardant’s designations. Ex. D (spreadsheet
 21 with Andersen designations, illustrating that first, fifth, and sixth entries on Natera’s were not
 22 designated). But the answer to a supposed difference in possible translations is not to throw the
 23 baby out with the bath water, but rather to let Natera present evidence of any supposed
 24 mistranslations or misinterpretations.

25 Natera cannot gainsay that Dr. Andersen’s testimony is important—and indeed, critical. It
 26 can point to no authority suggesting that a Danish Court’s *summary* of that testimony is superior
 27 to the actual *verbatim* testimony itself—much less any controlling authority that would *mandate*
 28 the use of a summary while *prohibiting* the actual testimony. What is left is a hyper-technical

1 complaint that a sworn interpreter was not sworn, and nit-picking disputes over a few snippets of
2 testimony. None of these complaints warrant exclusion of Dr. Andersen's testimony.

3 **V. Conclusion**

4 Natera's Motion should be denied, and the Court should allow the jury to hear from Dr.
5 Andersen.

6 Dated: November 3, 2024

7 **ALLEN OVERY SHEARMAN**
8 **STERLING US LLP**

9 **SAUL PERLOFF**
10 By: /s/ Saul Perloff
11 Saul Perloff

12 Attorney for Plaintiff
13 GUARDANT HEALTH, INC.

14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing document has been served on November 3, 2024, to the counsel of record via email to qe-natera-guardant@quinnemanuel.com.

Counsel for Defendants:

Kevin P.B. Johnson

Victoria F. Maroulis

Andrew J. Bramhall

Anne S. Toker

Valerie Lozano

Andrew Naravage

Ryan Landes

Elle Wang

Margaret Shyr

Ryan Hudash

Brian Cannon

Jocelyn Ma

Kaitlin Keohane

Victoria Par

/s/ *Saul Perloff*

Saul Perloff